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Mallinckrodt Inc. 675 McDonnell Boulevard HAZELWOOD, MO 63042			EXAMINER GERIDO, DWAN A	
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			1797	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/527,011	<b>Applicant(s)</b> BESING ET AL.	
	<b>Examiner</b> Dwan A. Gerido, Ph.D.	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11-16, 18 and 29-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11-16, 18 and 29-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5-31-2005, 6-1-2005</u> .                                     | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 12 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Regarding claim 12, it is unclear what applicant regards as of generally uniform thickness. For the purposes of examination generally uniform thickness will be interpreted as the thickness required shielding radiation.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 4, 8, 12, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Reich (US 5,519,931).
6. For claim 1, Reich teaches a container comprising an elongate base with inner and outer shells enclosing a shielding element (column 6 lines 20 and 21, figure 1 #22), and an elongate cap with inner and outer shells (column 6 lines 24 and 25, figure 1 #20) wherein the cap is removably attached to the base (column 6 lines 25-30, figure 1 #'s 30 and 36). Reich also teaches a portion of the cap overlapping a portion of the base shielding element (figures 1-3).

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7. For claim 4, Reich teaches the base and cap shielding elements formed from lead (column 7 lines 21-24).

8. For claim 8, Reich teaches a hollow base sized to accommodate a needle and barrel of a syringe, and a hollow cap sized to accommodate a plunger of a syringe (column 9 lines 6-8).

9. For claim 16, Reich teaches a portion of the base shielding element disposed about a portion of the outer shell of the cap (figure 7 #'s 60 and 62).

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 2, 3, and 11 rejected under 35 U.S.C. 103(a) as being unpatentable over Reich (US 5,519,931) in view of Kriesel (US 5,545,139).

14. With regards to claims 2 and 11 Reich teaches a container comprising an elongate base with inner and outer shells enclosing a shielding element (column 6 lines 20 and 21, figure 1 #22), and an elongate cap with inner and outer shells (column 6 lines 24 and 25, figure 1 #20) wherein the cap overlaps a portion of the base (figures 1-3), and is removably attached to the base (column 6 lines 25-30, figure 1 #'s 30 and 36). In addition, Reich teaches placing a label containing information about the sample on either the syringe body, sharps container, or the pharmaceutical pig (column 7 lines 55-67, column 10 lines 26-35). Reich does not teach a flexible sleeve placed on the outer shell of the base

Kriesel teaches a fluid container assembly wherein a flexible sleeve having a transparent portion is placed on the outer shell of the device (column 4 lines 11-14, 59-62 figure 1 #'s 30 and 52).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the pharmaceutical pig of Reich in view of Kriesel to utilize a flexible sleeve comprising a transparent portion and label in order to form a sterility barrier on the external portion of the device, and to create an external portion suited for imprinting a label as taught by Kriesel.

15. With regards to claim 3, Reich in view of Kriesel does not explicitly teach a label disposed between the flexible sleeve and the outer shell of the base. It would have been obvious

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to one of ordinary skill in the art at the time the invention was made to modify Reich in view of Kriesel wherein the label is disposed between the sleeve and the outer shell in order to prevent damage to or loss of information from the label due to repeated handling from a user or device.

16. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reich (US 5,519,931) in view of McCord (US 6,740,260).

17. With regards to claim 5, Reich does not teach a pharmaceutical pig wherein the base and cap shielding elements are formed from a metallic filled polymer.

McCord teaches a polymer-tungsten precursors composite utilized for forming radiation shields and insulators (Abstract, column 5 lines 47-50).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Reich in view of McCord by utilizing a metallic filled polymer to form the base and cap shielding elements in order to provide a wide variety of materials capable of shielding radiation.

18. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reich (US 5,519,931) in view of Fu et al., (US 7,268,359).

19. With regards to claim 6, Reich teaches a pharmaceutical pig wherein the upper and lower shields are welded to the upper and lower shells (column 8 lines 45-51). Reich does not teach the device made of stainless steel.

Fu et al., teach an apparatus for transporting pharmaceuticals wherein the upper and lower shells are made of stainless steel (column 9 lines 38-42).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Reich in view of Fu et al., to gain the advantage of providing a durable metal that is light in weight in order to aid in transporting the device.

20. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reich (US 5,519,931) in view of Fu et al., (US 7,268,359) as applied to claim 6 above, and further in view of Brenes (US 5,791,632).

21. With regards to claim 7, Reich in view of Fu et al., do not teach a device comprising a plurality of keyhole shaped slots in the cap, nor do they teach a plurality of screws in the base to form a sliding lock mechanism.

Brenes teaches a quick release slide lock mechanism wherein a plurality of screws and keyhole shaped slots comprise a sliding lock mechanism (column 3 lines 39-43, figure 1 #'s 32 and 34). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Reich in view of Fu et al., in further view of Brenes to gain the advantage of providing an easily detachable locking mechanism in order to separate the cap and base with minimal agitation of the syringe.

22. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reich (US 5,519,931) in view of Leicester et al., (GB 908,134).

23. With regards to claim 13, Reich does not teach a bayonet type interconnection between the cap and the base.

Leicester et al., teach a device for handling radioactive material wherein the cap and base portions display a bayonet type interconnection (page 2 lines 62-69).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Reich in view of Leicester et al., to utilize a bayonet type connection in order to provide a locking mechanism that can be easily removed with minimal disruption or disturbance of the syringe.

24. Claims 14 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reich (US 5,519,931) in view of Leicester et al., (GB 908,134) in further in view of Fu et al., (US 7,268,359).

25. With regards to claim 14, Reich does not teach a container comprising means for a bayonet type interconnection.

Leicester et al., teach a device for handling radioactive material wherein the cap and base portions display a bayonet type interconnection (page 2 lines 62-69).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Reich in view of Leicester et al., to utilize a bayonet type connection in order to provide a locking mechanism that can be easily removed with minimal disruption or disturbance of the syringe.

Reich in view of Leicester et al., do not teach a container made of stainless steel.

Fu et al., teach an apparatus for transporting pharmaceuticals wherein the upper and lower shells are made of stainless steel (column 9 lines 38-42).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Reich in view of Fu et al., to gain the advantage of providing a durable metal that is light in weight in order to aid in transporting the device.



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26. With regards to claim 18, Reich teaches a container wherein the base shielding element is tapered at the needle accommodating portion (column 8 lines 33-35). Reich does not teach a container in which the cap and base are formed from stainless steel, nor does he teach a bayonet type connection between the cap and the base.

Fu et al., teach an apparatus for transporting pharmaceuticals wherein the upper (cap) and lower (base) shells are made of stainless steel (column 9 lines 38-42).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Reich in view of Fu et al., to gain the advantage of providing a durable metal that is light in weight in order to aid in transporting the device.

Reich in view of Fu et al., do not teach a bayonet type connection between the cap and base of the device.

Leicester et al., teach a device for handling radioactive material wherein the cap and base portions display a bayonet type interconnection (page 2 lines 62-69).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Reich in view of Fu et al., in further view of Leicester et al., to utilize a bayonet type connection in order to provide a locking mechanism that can be easily removed with minimal disruption or disturbance of the syringe.

27. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reich (US 5,519,931) in view of Brenes (US 5,791,632).

With regards to claim 15, Reich teaches a pharmaceutical pig comprising an elastomeric ring compressed between the upper and lower shells (column 6 lines 65 and 66, figure 1 #42). It would have been obvious to one of ordinary skill in the art at the time the invention was made to

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place the elastomeric ring between the cap and the base in order to provide an air and fluid tight seal. Reich does not teach a plurality of keyhole slots and a plurality of screws to form a locking mechanism.

Brenes teaches a quick release slide lock mechanism wherein a plurality of screws and keyhole shaped slots comprise a sliding lock mechanism (column 3 lines 39-43, figure 1 #'s 32 and 34). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Reich in view of Fu et al., in further view of Brenes to gain the advantage of providing an easily detachable locking mechanism in order to separate the cap and base with minimal agitation of the syringe

28. Claims 29, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reich (US 5,519,931) in view of Leicester et al., (GB 908,134).

29. With regards to claim 29, Reich teaches an assembly for transporting a radiopharmaceutical comprising a syringe having a needle, barrel and a plunger (figure 3). Reich also teaches a pharmaceutical pig comprising elongate base with inner and outer shells enclosing a shielding element (column 6 lines 20 and 21, figure 1 #22), and an elongate cap with inner and outer shells (column 6 lines 24 and 25, figure 1 #20) wherein the inner and outer shells of the both the cap and base encloses the shielding elements (figure 3 #'s 16 and 20, 18 and 22). In addition, Reich teaches a hollow base sized to accommodate a needle and barrel of a syringe, and a hollow cap sized to accommodate a plunger of a syringe (column 9 lines 6-8). Reich does not teach an assembly comprising means for enabling a bayonet type interconnection.

Leicester et al., teach a device for handling radioactive material wherein the cap and base portions display a bayonet type interconnection (page 2 lines 62-69).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Reich in view of Leicester et al., to utilize a bayonet type connection in order to provide a locking mechanism that can be easily removed with minimal disruption or disturbance of the syringe.

30. With regards to claim 32, Reich teaches the base shielding element tapered at the needle accommodating portion (column 8 lines 33-35), and a cap of generally uniform thickness.

31. With regards to claim 33, Reich teaches a portion of the cap shielding element overlapping a portion of the base shielding element (figure 1 #'s 38 and 36, figure 2).

32. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reich (US 5,519,931) in view of Leicester et al., (GB 908,134) as applied to claim 29 above, and further in view of Brenes (US 5,791,632).

33. With regards to claim 30, Reich teaches a pharmaceutical pig comprising an elastomeric ring compressed between the upper and lower shells (column 6 lines 65 and 66, figure 1 #42). It would have been obvious to one of ordinary skill in the art at the time the invention was made to place the elastomeric ring between the cap and the base in order to provide an air and fluid tight seal. Reich does not teach a plurality of keyhole slots and a plurality of screws to form a locking mechanism.

Brenes teaches a quick release slide lock mechanism wherein a plurality of screws and keyhole shaped slots comprise a sliding lock mechanism (column 3 lines 39-43, figure 1 #'s 32 and 34). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Reich in view of Leicester et al., in further view of Brenes to gain the

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advantage of providing an easily detachable locking mechanism in order to separate the cap and base with minimal agitation of the syringe.

34. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reich (US 5,519,931) in view of Leicester et al., (GB 908,134) as applied to claim 29 above, and further in view of Kriesel (US 5,545,139).

With regards to claim 31, Reich does not teach a flexible sleeve with a transparent portion disposed on the outer shell, and a label disposed between the flexible sleeve in the base.

Kriesel teaches a fluid container assembly wherein a flexible sleeve having a transparent portion is placed on the outer shell of the device (column 4 lines 11-14, 59-62 figure 1 #'s30 and 52).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the pharmaceutical pig of Reich in view of Kriesel to utilize a flexible sleeve comprising a transparent portion and label in order to form a sterility barrier on the external portion of the device, and to create an external portion suited for imprinting a label as taught by Kriesel.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwan A. Gerido, Ph.D. whose telephone number is (571)270-3714. The examiner can normally be reached on Monday - Friday, 9:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DAG

/Jill Warden/  
Supervisory Patent Examiner, Art Unit 1797